K093021

510(k) SUMMARY

Summary of Safety and Effectiveness for the Atlantis Slit Lamp

submitted by
USOphthalmic, LLC
9990 NW 14th Street Unit # 105
Doral, Florida 33172
Phone: (305) 969-4545

JAN 28 2010

Contact Person: Gustavo Lancewicki
Device Trade Name: Atlantis Slit Lamp
Common Name: Slit Lamp
Classification Name: Biomicroscope, Slit-lamp, AC-powered per 21 CFR § 886.1850

Identification of a Legally Marketed Predicate Device

The USOphthalmic, LLC Atlantis Slit Lamp is substantially equivalent to 66 Vision-Tech YZ Slit Lamp that is legally marketed and distributed by Suzhou 66 Vision-Tech Co., LTD pursuant to premarket notification K033190.

Device Description

The Atlantis Slit Lamp is an AC-power slit lamp biomicroscope intended for use in eye examination There are 2 models 2000 and 2000 Plus. These models differ only in the supplied accessories (beam-splitter, camera mount and observation tube). All models have the same operating characteristics and intended use.

Intended Use

The Atlantis Slit Lamp is an AC-power slit lamp biomicroscope intended for use in eye examination of the anterior eye segment, from the cornea epithelium to the posterior capsule. It is used to aid in the diagnosis of diseases or trauma which affect the structural properties of the anterior eye segment.

Summary of Technological Characteristics

An 8-point comparison of technological characteristics of the USOphthalmic, LLC Atlantis Slit Lamp and the predicate devices was performed. The devices were found to be substantially equivalent.

Summary of Performance Data

The USOphthalmic, LLC Atlantis Slit Lamp complies with the requirements of listed FDA Recognized Consensus Standards.

- ISO 10939:2007, Ophthalmic instruments -- Slit-lamp microscopes
- IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety

The USOphthalmic, LLC Atlantis Slit Lamp is substantially equivalent to the 66 Vision-Tech YZ Slit Lamp that is legally marketed and distributed by Suzhou 66 Vision-Tech Co., LTD. This has been demonstrated through a 8-point technological comparison of features.

Because the USOphthalmic, LLC Atlantis Slit Lamp meets the requirements of the stated standards and embody technological characteristics essentially identical to the predicate device, we believe the device is safe and effective and performs as well as or better than the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

JAN 28 2010

US Ophthalmic LLC
c/o Mr. Al Weisenborn
Al Weisenborn Medical Device Consulting
19526 East Lake Dr.
Miami, Florida 33015-2218
United States

Re: K093021
Trade/Device Name: Atlantis Slit Lamp, models 2000 and 2000 Plus
Regulation Number: 21 CFR 886.1850
Regulation Name: AC-powered slitlamp biomicroscope
Regulatory Class: Class II
Product Code: HJO
Dated: December 23, 2009
Received: December 24, 2009

Dear Mr. Weisenborn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K093021

Device Name: Atlantis Slit Lamp

Indications for Use:

The Atlantis Slit Lamp is an AC-power slit lamp biomicroscope intended for use in eye examination of the anterior eye segment, from the cornea epithelium to the posterior capsule. It is used to aid in the diagnosis of diseases or trauma which affect the structural properties of the anterior eye segment.

Prescription Use X AND/OR Over-The-Counter Use
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K093021